

**INTEGRATIVE THERAPEUTICS INC.™**NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 • F: 503.582.0467

**ENZYMATIC THERAPY™****&  
PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY™**What **Better** feels like.™

0274 5 APR -7 P2:30

March 25, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

MAR 30 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM Menopause Formula™*	AM Formula: Black Cohosh for natural hormonal support and relief of occasional hot flashes and mood swings.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer

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## ENZYMATIC THERAPY

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM Menopause Formula™*	AM Formula: Green Tea for energy, weight management and to protect against free-radical damage.*	Green Tea (Camellia sinensis) Leaf Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

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Sincerely,

Michael P. Devereux  
Chief Financial Officer



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GREENSBORO, NC

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM Menopause Formula™*	PM Formula: Black Cohosh to offset hormonal fluctuations that can result in occasional night sweats.*	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

3/25/05

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Sincerely,

Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY

MANUFACTURED

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM Menopause Formula™*	PM Formula: Valerian for relaxation and deep sleep*	Valerian (Valeriana officinalis) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

3/25/05

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March 26, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
AM/PM Menopause Formula™*	PM Formula: L-Theanine to alleviate nighttime muscle tension and promote restful sleep.*	L-Theanine

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

3/26/05

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